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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Peter F. Whittington

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Brinks Hofer Gilson & Lione
P.O. Box 10395
Chicago, IL 60610

EXAMINER

VU, QUYNH-NHU HOANG

ART UNIT

PAPER NUMBER

3763

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/809,741	Applicant(s) WHITINGTON, PETER F.	
	Examiner QUYNH-NHU H. VU	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 2,4,5,19,21,29 and 3245 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,6-18,20,22-28,30 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/24/04 & 9/22/05</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, Species A (Figs. 1-6), subspecies vi (Figs. 5A-6), claims 1, 3, 6-18, 20, 22-28 and 30-41 in the reply filed on 2/12/08 is acknowledged.

It is noted that there was typo error made by Examiner. The correction is Group I: claims 1-31, drawn to a delivery device. Group II: claims 32-45 drawn to a method of delivering nutrition to a patient.

Examiner called the Attorney for the correction on 03/20/08.

Since Applicant elected Group I, which is device claims, and Species A, subspecies vi. Therefore, claims 1, 3, 6-18, 20-28 and 30-31 will be examined.

Claims 2, 4-5, 19, 21, 29, 32-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Species 2-3, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/12/08.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description:

External diameter 20, external diameter 22, 24 (see para 0037).

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

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Claim Objections

Claim 9 is objected to because of the following informalities: No where in the specification discloses that the expandable, digestible member comprises **meat**. Does Applicant mean that “the expandable, digestible member comprises **metal**”? Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No where n the Specification discloses that: an external diameter of the expandable, digestible member in a collapsed state does not exceed an external diameter of the catheter by more than about twenty percent, ten percent, fifty percent, thirty percent as in claims 10-13.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 6, 14-18, 22, 25-28 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Potter (US 4,781,704).

Potter discloses a delivery device comprising: a substantially flexible catheter 10 or 15 having first end and a second end; wherein the catheter comprises a biocompatible thermoplastic polymer (col. 4,

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lines 40-48); and an expandable, digestible member 13 connected to the first end of the catheter, which is substantially dehydrated in a collapsed state, and which swell upon past an obstruction such as gastric juices. (col. 5, lines 12-30).

Additionally, it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e., "substantially dehydrated in a collapsed state, and which swells upon contact with gastric juices", a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim, see *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974)

Regarding claim 15, it is noted that any the catheter having substantially rigid character, or the catheter containing some degree of rigidity to able inserted into the body.

Regarding claim 22, a side surface of the first end comprises means for securing the expandable, digestible member (col. 4, lines 57-65).

Regarding claim 25-28, a connector 20 is connected to the second end of the catheter 15 and wherein the connector comprises a plurality of ports 21, 22; the connector is selected from Y-shaped connector; wherein ports 20-21 are female adapter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7, 23 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Potter in view of Bachaer et al. (US 5,599,307).

Potter discloses the claimed invention except for the expandable, digestible member comprises fibrous, an erodable coating surrounded the expandable, digestible member.

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Bachaer discloses that the expandable member comprises fibrous layer 43a (col. 10, lines 21-25); an erodable coating (releasable membrane) 43b is positioned outside layer (see Fig. 11); wherein the coating 43b formed of sugar-based material (col. 7, lines 45-54) which is same material of erodable coating of Applicant as described in para [0048].

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Potter with a fibrous material and an erodable coating to allow the fluid to pass through expandable wall.

Claims 7-9, 10-13, 20, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Potter.

Regarding claims 7-9, Potter discloses the claimed invention except for the expandable, digestible member comprises fibrous, collagen or metal. However, It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the expandable, digestible member comprises fibrous, collagen or metal, as discussed above, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Regarding claims 10-13, as best as understood, Potter discloses the claimed invention except for the expandable in a collapsed state does not exceed an external diameter of the catheter by more than about 10-50%. It would have been obvious to one having ordinary skill in the art at the time of the invention was made to provided the external diameter of expandable member, as described in claims 10-13, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Regarding claims 20, 22, Potter discloses the claimed invention. Potter further discloses the expandable, digestible member is connected to the first end by a seal (col. 4, lines 57-61), but does not specifically disclose a biocompatible adhesive. However, it is well-known in the art use of biocompatible adhesive, as Applicant admitted in para 0046. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the adhesive as discussed above, since it has been held to be within the general skill of a worker in the art to select a known material on the

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basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claims 23 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Potter in view of Maniar et al. (US 5,846,525).

Potter discloses the claimed invention except for that an erodable coating at least a portion of the expandable, digestible member; whereby the erodable coating degenerates upon contacting contents of a stomach.

Maniar discloses an erodable coating can be designed to erode in a selected region of the gastrointestinal tract, thereby providing an additional layer of protection for the biopolymer while in the gastrointestinal tract. An erodable coating also can be an enteric coating, which allows a composition/material to pass through the stomach without significant alteration.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Potter with a erodable coating, as taught by Maniar, in order to protecting the biopolymer member while in the gastrointestinal tract.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Potter in view of Maniar et al. and further in view of Barr (US 6,514,487).

Potter in view of Maniar discloses the claimed invention except for the erodable coating comprises a topical analgesic.

Barr discloses that topical analgesic useful for treating skin discomforts.

As we know that when the device is inserted into stomach, I will cause patient uncomfortable and painful. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the topical analgesic in to the device of Potter in view Maniar, as taught by Barr for reducing the pains.

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
Art Unit 3763